

## REMARKS

As for the status of the application, Claims 1-14 are pending in this application. Reconsideration of this application is respectfully requested. It is respectfully submitted that this response does not require further searching on the part of the Examiner. It is also respectfully submitted that this response places this application in condition for allowance, or in any event, places it in better condition for consideration on appeal.

Claims 1, 2, 7, 8, and 11-14 were rejected under 35 U.S.C. § 102(e) as being anticipated by US Patent No. 3,826,254 issued to Mellor. The Mellor patent discloses in its Summary of the Invention section that "the appliance comprises a lengthwise elongated pad having first and second elongated sections, the second section defining a flap extending lengthwise beyond the first section to be folded back over one side of the first section and over the needle, catheter or butterfly device oriented to extend crosswise of the pad; first pressure sensitive adhesive means on the opposite side of the first section to adhere the first section to a patient's body; and second pressure sensitive adhesive means on the pad to adhere the flap to the pad first section and to be adherent to the retained device oriented as defined. Also, peel-off backer strip means may typically be applied to the first and second pressure sensitive adhesive means, as will appear. As a result, rapid and firm retention of the needle or catheter to the patient's body is enabled by means of a single appliance or pad, with the danger of undesirable needle or catheter inadvertent rotation or disattachment substantially eliminated."

It is respectfully submitted that the Mellor pad is constructed as a single piece of material that is folded back upon itself to hold a needle, catheter or butterfly device. The Mellor patent discloses in column 2, lines 19-20 that the "pad may consist, for example, of a layer of porous plastic foam, as for example polyurethane". A "first pressure sensitive adhesive means" is used to adhere the pad to a patient's body. A "second pressure sensitive means" is used to adhere the folded flap (second section) to the first section.

Claim 1 calls for a tubing cuff for securing a tube to a limb of a patient, comprising:

- a layer of porous, cloth-like material;
- a layer of porous foam rubber secured to one side of the layer of porous, cloth-like material;
- a reclosable fastener for securing distal ends of the cuff together; and
- a bendable adhesive layer having an adhesive surface attached to the porous, cloth-like material on a side opposite to the layer of porous foam rubber.

With regard to Claims 1, it is respectfully submitted that there is no disclosure or suggestion in the Mellor patent regarding the use of two independent layers of different material to form the appliance. The Mellor patent clearly discloses that the appliance is made of a single layer of material ("a layer of porous plastic foam") that is folded back upon itself to secure a needle, etc. The present invention is made of two layers comprising a layer of porous foam rubber secured to one side of a layer of porous, cloth-like material. [Emphasis added]

It is respectfully submitted that there is no disclosure or suggestion in the Mellor patent regarding the use of "cloth-like material" in the appliance. The term "cloth" is not used in the Mellor patent.

There is no disclosure or suggestion in the Mellor patent regarding the use of "porous foam rubber" in the appliance. While the Mellor patent states that the "pad may consist, for example, of a layer of porous plastic foam, as for example polyurethane", it is respectfully submitted that this is not a disclosure or suggestion of the use of "porous foam rubber". Polyurethane is not a porous foam rubber material. Furthermore, the term "rubber" is not used in the Mellor patent.

Furthermore, the Mellor article is secured to a patient's body using adhesive. This is clearly not the case with the present invention, which secures and stabilizes I.V. tubing to a patient's limb without the use of adhesive material, as is stated in the Summary of the Invention section, for example, of the present application.

In view of the above discussion, and with specific regard to Claim 1, it is respectfully submitted that the Mellor patent does not disclose or suggest a tubing cuff comprising "a layer of porous, cloth-like material" and "a layer of porous foam rubber secured to one side of the layer of porous, cloth-like material", as is recited in Claim 1.

In view of the above discussion, and with regard to Claim 1, it is respectfully submitted that the Mellor patent does not disclose or suggest "a layer of porous foam rubber secured to one side of the layer of porous, cloth-like material", or "a bendable adhesive layer having an adhesive surface attached to the porous, cloth-like material on a side opposite to the layer of porous foam rubber", as is recited in Claim 1.

Therefore, it is respectfully submitted that the invention recited in Claim 1 is not disclosed or suggested by the Mellor patent. It is therefore respectfully submitted that the invention recited in Claim 1 is not anticipated by, nor is it obvious in view of the Mellor patent. Withdrawal of the Examiner's rejection of Claim 1 is respectfully requested.

With regard to Claim 2, it is respectfully submitted that the Mellor patent does not disclose or suggest the use of a microporous film layer as the primary strap layer. The terms "microporous" or "microporous film" are not used in the Mellor patent. Therefore, it is respectfully submitted that the Mellor patent does not disclose or suggest that "the layer of porous, cloth-like material comprises microporous film", as is recited in Claim 2.

With regard to Claim 7, it is respectfully submitted that the Mellor patent does not disclose or suggest that "the layer of porous foam rubber comprises non-skid porous foam rubber", as is recited in Claim 7. These terms are not used in the Mellor patent.

With regard to Claims 8 and 11-14, it is respectfully submitted that the Mellor patent does not disclose or suggest the use of a reclosable fastener that comprises "hook and loop materials". There are no hook and loop materials discussed in the Mellor patent. The terms "hook" and "loop" are not used in the Mellor patent.

Dependent Claims 2, 7, 8, and 11-14 are also considered patentable based upon their dependence from allowable Claim 1. Therefore, it is respectfully submitted that the inventions recited in Claims 2, 7, 8, and 11-14 are not disclosed or suggested by the Mellor patent, and that the inventions in Claims 2, 7, 8, and 11-14 are not anticipated by, nor they obvious in view of the Mellor patent. Therefore, withdrawal of the Examiner's rejection of Claims 2, 7, 8, and 11-14 is respectfully requested.

Claims 1-12 and 14 were rejected under 35 U.S.C. § 102(e) as being anticipated by US Patent No. 6,645,185 issued to Bird et al. The Bird et al. patent corresponds to previously cited US Patent Publication No. 2002/0165495,.

The Examiner's position is that "Bird teaches a tubing cuff with a layer of porous material 12 a layer of foam rubber (plastic) 16 secured to one side of the layer porous material a closable fastener for securing distal ends of the cuff together, and a bendable adhesive layer 20 having an adhesive surface attached to the porous material on the opposite side to the layer of rubber/plastic. (Figures 1-10) where the fasteners comprise of hook and loop material. And the porous material is hypoallergenic."

The Bird et al. patent discloses "An improved anchoring appliance for detachably securing a catheter or other elongate or tube-like member to the limb of a body is disclosed. A primary strap with a slip-resistant surface is configured for adjustable encircling attachment to the limb. The slip-resistant surface directly engages the limb and includes material that resists slippage of the strap longitudinally along the limb. A secondary anchoring member attached to the strap is configured to detachably retainably engage and hold a catheter or other elongate or tube-like member in a desired position relative to the strap. The anchoring appliance preferably has at least its slip-resistant surface made of non-allergenic materials." (see Abstract)

The Bird et al. patent states at column 4, lines 34-51, that "The tube-retaining band ... has a primary strap portion 11 ... to which a tube device 3 is to be secured", and that "The primary strap 11 is preferably constructed of an elastic woven, knit, or webbing material", and that "an outer surface 12 of the band, illustrated as the upper-most surface in FIG. 2 is configured as a looped material, typically or brushed nylon or knit or woven loop material having loops extending outwardly from the surface". It is stated in Claim 18 that "said primary strap material is porous to air passage through said slip-resistant first surface".

With regard to reference numeral 13, the Bird et al. patent states at column 4, lines 51-58, that "The opposite or inner surface 13 of the primary strap 11 is configured to directly engage the skin of the limb or other member encircled by the primary strap 11. The inner surface 13 of the primary strap 11 is constructed of or may, or may not carry a soft lining material which may, for example, be in the form of a Helanca™ backing or other soft material which is comfortable and non-allergenic to the wearer's skin ..."

The Bird et al. patent states at column 5, lines 54-59, that "A slip-resistant material [identified by reference numeral 16] such as silicone may be applied to the inner surface 13 of

the primary strap 11 to prevent or retard slippage between the inner surface 13 of the primary strap 11 and the outer limb surface to which the primary strap is affixed.", and at column 6, lines 6-11, that "In a preferred embodiment of the invention, the slip-resistant material 16 is in the nature of silicone material; however, it will be understood by those skilled in the art that other materials such as for example, neoprene or latex rubber, could equally well be used."

With regard to layer 24, the Bird et al. patent states at column 7, lines 40-46, that "A length of an elastic or nonelastic "hook" fastening material 24 is secured by stitching 25 to the outer surface 20b of the secondary strap 20 at its distal end 20c. The hook fastening material 24 is oriented relative to the secondary strap 20 such that its hook-like barbs face in the same direction as the inner surface 20a of the secondary strap 20."

However, as for the slip-resistant material used in the Bird et al. device, while it is stated that neoprene or latex rubber may be used, it is respectfully submitted that there is no specific disclosure or suggestion in the Bird et al. patent that the slip-resistant material comprises "a layer of porous foam rubber". The term "foam" is not used in the Bird et al. patent.

Furthermore, as for the fastener used in the Bird et al. device, it is stated at column 5, lines 15-20, that "A short strip 15 of "hook"-type fastener material ... is secured by stitching 14 to the inner surface 13 of the primary strap 11 adjacent its second end 11b, and longitudinally extends outwardly therefrom to a distal end 15a." It is stated at column 4, lines 46-48 of the Bird et al. patent that "an outer surface 12 of the band, ... is configured as a looped material." Thus, the entire outer surface of the primary strap is made of loop material. It is stated in paragraph 41 that "the fastener material 15 ... overlaps and engages the loops of the outer surface 12 of the primary strap as the strap encircles the limb."

It is stated at column 7, lines 1-20, that the "secondary strap portion 20 is preferably configured of an elastic webbing material", that "The inner surface 20a of the secondary strap 20 is entirely or partially lined with a layer of slip-resistant material such as silicone, neoprene or latex", that In the preferred embodiment, the slip-resistant material is of ribbed configuration as illustrated in FIG. 4, wherein the ribs extend longitudinally of the secondary strap 20.", and that "In the preferred embodiment, the secondary strap portion material of the preferred embodiment is generally referred to as a woven or knit elastic that is commercially available." It is stated in 7, lines 40-44, that "A length of an elastic or nonelastic "hook" fastening material 24 is secured by stitching 25 to the outer surface 20b of the secondary strap 20 at its distal end 20c."

Thus, it is clear from reading the Bird et al. patent that the secondary strap portion 20 which is used to secure a tube is not made of bendable adhesive material. There is no disclosure or suggestion in the Bird et al. patent regarding the use of a bendable adhesive layer to secure the tube. In fact,, the term "adhesive" is not used in the Bird et al. patent.

In view of the above discussion, and with regard to Claim 1, it is respectfully submitted that the Bird et al. patent does not disclose or suggest "a layer of porous foam rubber secured to

one side of the layer of porous, cloth-like material", or "a bendable adhesive layer having an adhesive surface attached to the porous, cloth-like material on a side opposite to the layer of porous foam rubber", as is recited in Claim 1.

Therefore, it is respectfully submitted that the invention recited in Claim 1 is not disclosed or suggested by the Bird et al. patent. It is therefore respectfully submitted that the invention recited in Claim 1 is not anticipated by, nor is it obvious in view of the Bird et al. patent. Withdrawal of the Examiner's rejection of Claim 1 is respectfully requested.

With specific regards to Claim 2, while Claim 13 of the Bird et al. patent states that "said primary strap material is porous to air passage through said first inner surface", this is the only use of the term "porous" in the Bird et al. patent, and there is no specific disclosure relating thereto in the specification. Furthermore, it is respectfully submitted that the Bird et al. patent does not disclose or suggest the use of a microporous film layer as the primary strap layer. The terms "microporous" or "microporous film" are not used in the Bird et al. document. Therefore, it is respectfully submitted that the Bird et al. patent does not disclose or suggest that "the layer of porous, cloth-like material comprises microporous film", as is recited in Claim 2.

With specific regards to Claim 7, while the Bird et al. patent states at column 5, lines 54-55, that a "slip-resistant material such as silicone may be applied to the inner surface 13 of the primary strap 11", and that "the slip-resistant material 16 is in the nature of silicone material; however, it will be understood by those skilled in the art that other materials such as for example, neoprene or latex rubber, could equally well be used," it is respectfully submitted that the Bird et al. patent does not disclose or suggest anything regarding the use of a "layer of non-skid porous foam rubber", as is recited in Claim 7.

With regards to Claim 14, it is respectfully submitted that the Bird et al. patent does not disclose or suggest that a layer of porous foam rubber is placed against a patient's limb and secured by a reclosable fastener, and wherein a tube is laid on exposed adhesive of the bendable adhesive layer, which bendable adhesive layer is wrapped around the tube to secure it to the cuff. No adhesive layer is disclosed or suggested in the Bird et al. patent

Therefore, it is respectfully submitted that the Bird et al. patent does not disclose or suggest a tubing cuff "wherein the layer of porous foam rubber is placed against the patient's limb and secured by the reclosable fastener, and wherein a tube is laid on exposed adhesive of the bendable adhesive layer, which bendable adhesive layer is wrapped around the tube to secure it to the cuff", as is recited in Claim 14.

Dependent Claims 2-12 and 14 are also considered patentable based upon their dependence from allowable Claim 1. Therefore, it is respectfully submitted that the inventions recited in Claims 2-12 and 14 are not disclosed or suggested by the Bird et al. patent, and that the inventions in Claims 2-12 and 14 are not anticipated by, nor they obvious in view of the Bird et al. patent. Therefore, withdrawal of the Examiner's rejection of Claims 2- 12 and 14 is respectfully requested.

Claims 1-12 and 14 rejected under 35 U.S.C. § 102(b) as being anticipated by US Patent No. 5,941,856 issued to Kovacs et al.

The Kovacs et al. patent discloses a "medical conduit holder for releasably securing and reattaching a medical conduit, for example, a Foley catheter, to the limb of a patient. The holder includes a non-stretchable stabilizing member having a looped fabric surface, and attached to a stretchable primary strap to form an enclosed nonstretchable area of the primary strap. The primary strap is configured for attachment to the limb of the patient. The holder further includes a secondary strap attached to both the platform and the primary strap, preferably at the center of the secondary strap. The secondary strap has a first portion with a window, and an engagement portion dimensioned to loop around the conduit and fit through the window. In use, the engagement portion is looped over the medical conduit and through the window, such that the hooked surface of the engagement portion contacts the looped surface of the stabilizing member in order to secure the medical conduit. The first portion is then likewise looped over the medical conduit, such that the hooked surface of the first portion contacts the looped fabric surface of the platform. The stabilizing member resists buckling in order to retain the medical conduit in place, with little movement of the conduit relative to the primary strap." (see Abstract)

With regard to Claim 1, it is respectfully submitted that the Kovacs et al. patent does not disclose or suggest the use of a layer of porous foam rubber secured to one side of a layer of porous, cloth-like material, as is recited in Claim 1. The Kovacs et al. patent does not use the terms "porous", "foam", "rubber", "porous foam", or "porous foam rubber".

It is respectfully submitted that the Kovacs et al. patent does not disclose or suggest the use of a bendable adhesive layer having an adhesive surface attached to the porous, cloth-like material on a side opposite to the layer of porous foam rubber, as is recited in Claim 1. The Kovacs et al. patent does not use the terms "adhesive" or "adhesive surface".

The Kovacs et al. patent does not disclose or suggest that the porous foam rubber layer is disposed on one side of a layer of porous, cloth-like material while a bendable adhesive layer is disposed on an opposite side of the layer of porous, cloth-like material.

Also, as is stated at column 5, lines 5-15 of the Kovacs et al. patent "a secondary strap 18" that "includes a first rectangular portion 42 having a [window 44] therethrough, and a second, elongated engagement portion 46 which is preferably formed as an integral member with the first portion and preferably sized so as to be insertable within window 44." It is respectfully submitted that this secondary strap 18 does not correspond to a bendable adhesive layer, as is recited in Claim 1.

In view of the above discussion, and with regard to Claim 1, it is respectfully submitted that the Kovacs et al. patent does not disclose or suggest "a layer of porous foam rubber secured to one side of the layer of porous, cloth-like material", or "a bendable adhesive layer having an adhesive surface attached to the porous, cloth-like material on a side opposite to the layer of porous foam rubber", as is recited in Claim 1.

Therefore, it is respectfully submitted that the invention recited in Claim 1 is not disclosed or suggested by the Kovacs et al. patent. It is therefore respectfully submitted that the invention recited in Claim 1 is not anticipated by, nor is it obvious in view of the Kovacs et al. patent. Withdrawal of the Examiner's rejection of Claim 1 is respectfully requested.

With regard to Claims 2-5, it is respectfully submitted that the Kovacs et al. patent does not disclose or suggest that "the layer of porous, cloth-like material comprises microporous film". There is no disclosure or suggestion of using microporous film contained in the Kovacs et al. patent.

With regard to Claim 7, it is respectfully submitted that the Kovacs et al. patent does not disclose or suggest that "the layer of porous foam rubber comprises non-skid porous foam rubber". These terms are not used in the Kovacs et al. patent.

With regard to Claim 13, it is respectfully submitted that the Kovacs et al. patent does not disclose or suggest that the "adhesive layer has a protective layer that covers adhesive material and which is removed to expose the adhesive material of the adhesive layer." There is no adhesive layer discussed in the Kovacs et al. patent.

With regards to Claim 14, it is respectfully submitted that the Kovacs et al. patent does not disclose or suggest that a layer of porous foam rubber is placed against a patient's limb and secured by a reclosable fastener, and wherein a tube is laid on exposed adhesive of the bendable adhesive layer, which bendable adhesive layer is wrapped around the tube to secure it to the cuff. No adhesive layer is disclosed or suggested in the Kovacs et al. patent

Dependent Claims 2-12 and 14 are also considered patentable based upon their dependence from allowable Claim 1. Therefore, it is respectfully submitted that the inventions recited in Claims 2-12 and 14 are not disclosed or suggested by the Kovacs et al. patent, and that the inventions in Claims 2- 12 and 14 are not anticipated by, nor they obvious in view of the Kovacs et al. patent. Therefore, withdrawal of the Examiner's rejection of Claims 2-12 and 14 is respectfully requested.

Claims 4 and 6 were rejected under 35 U.S.C. § 103(a) as being unpatentable over US Patent No. 3,826,254 issued to Mellor in view of US Patent No. 5,342,317 issued to Claywell. The Claywell patent is cited as teaching a tubing cuff with a hypoallergenic layer, which the Examiner concluded could have been used in the Mellor device.

It is respectfully submitted that the Mellor and Claywell references, taken singly or together, do not disclose or suggest the invention recited in Claim 1, for the reasons argued above. Therefore, it is respectfully submitted that the Bird et al. and Claywell references, taken singly or together, do not disclose or suggest the inventions recited in Claims 4 and 6.

Furthermore, dependent Claims 4 and 6 are considered patentable based upon their dependence from allowable Claim 1. Therefore, it is respectfully submitted that the inventions recited in Claims 4 and 6 are not obvious in view of the Mellor or Claywell patents, taken singly or together. Withdrawal of the Examiner's rejection of Claims 4 and 6 is respectfully requested.

Claims 5, 9 and 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over US Patent No. 3,826,254 issued to Mellor in view of US Patent No. 5,879,335 to Martinez et al. The Martinez patent is cited as teaching a woven loop with a durable backing layer, which the Examiner concluded could have been used in the Bird et al. device.

It is respectfully submitted that the Mellor and Martinez et al. references, taken singly or together, do not disclose or suggest the invention recited in Claim 1, for the reasons argued above. Therefore, it is respectfully submitted that the Mellor and Martinez et al. references, taken singly or together, do not disclose or suggest the inventions recited in Claims 5, 9 and 10.

In addition, dependent Claims 5, 9 and 10 are considered patentable based upon their dependence from allowable Claim 1. Therefore, it is respectfully submitted that Claims 5, 9 and 10 are not obvious in view of the Mellor or Martinez patent, taken singly or together. Withdrawal of the Examiner's rejection of Claims 5, 9 and 10 is respectfully requested.

The prior art heretofore made of record and not relied upon is considered pertinent to applicant's disclosure to the extent indicated by the Examiner.

In view of the above, it is respectfully submitted that all pending Claims are not anticipated by, nor are they obvious in view of the cited references, taken singly or together, and are therefore patentable. Accordingly, it is respectfully submitted that the present application is in condition for allowance. Reconsideration and allowance of this application are earnestly solicited. It is again respectfully submitted that this response does not require further searching by the Examiner, and places this application in condition

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Kenneth W. Float", with a stylized flourish at the end.

Kenneth W. Float  
Registration No. 29,233

The Law Offices of Kenneth W. Float  
2095 Hwy. 211 NW, Suite 2F #356  
Braselton, GA 30517  
Telephone: (949) 257-7964  
Facsimile: (770) 867-0082  
E-mail address: kwfloat@floatlaw.com